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**Duke University
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Research Update

Institute for Clinical and Epidemiological Research

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Silke Schmidt Joins Study with VA ALS National Registry

Health Services Research would like to welcome Silke A. Schmidt, Ph.D., who will be working with the National Registry of Veterans with Amyotrophic Lateral Sclerosis (ALS) through a five-year National Institute for Environmental Health Sciences (NIEHS) grant. Dr. Schmidt, a faculty member of Duke University's Center for Human Genetics, will study the genetic epidemiology of ALS among veterans.

"Studies of ALS in Guam and other Western Pacific islands support the hypothesis that gene-environment interaction may play a substantial role in the development of ALS," says Dr. Schmidt. "Several genes responsible for the familial form of ALS have been identified, but the majority of ALS is sporadic and has a complex etiology, with contributions from both genetic and environmental factors."

In addition to being on the faculty of Duke's Center for Human Genetics, Dr. Schmidt is an assistant research professor of medicine at Duke University Medical Center. She has had graduate and postdoctoral training in genetic epidemiology and has a particular research interest in examining gene-environment interactions in complex human diseases. She also has extensive experience in the management and statistical analysis of large collaborative genetic-epidemiologic studies of breast cancer, early-onset cardiovascular disease, multiple sclerosis, and age-related macular degeneration.

Co-investigators on the NIEHS-funded project include Eugene Oddone, M.D., who is the principal investigator for the ALS Registry, and Kelli Dominick, Ph.D., both of Durham's HSR&D Center of Excellence in Primary Care, and Jeffrey M. Vance, M.D., Ph.D., of Duke's Center for Human Genetics.

For her study, Dr. Schmidt hopes to recruit 1,500 ALS registry patients to be matched to 3,000 veterans without ALS by age, sex,

ethnicity and branch of military service. Study subjects will be asked to give a blood sample and complete an environmental risk factor questionnaire that will include military-specific exposure assessment in order to compare genetic and environmental exposures of both groups. "Essentially, I will evaluate whether there are certain environmental exposures that may trigger the development of ALS in genetically susceptible individuals," says Dr. Schmidt. "At this point, it's unknown what these genetic susceptibilities might be, which genes are involved, what kinds of variations in these genes may be important, and which environmental factors may play a role."

Dr. Schmidt's long-term interest in the role of gene/environmental interactions in complex human diseases attracted her to the study, as did its size and scope. "The registry is a great resource because it will assemble a very large population of patients," says Dr. Schmidt. "Gene-environment interaction studies need large sample sizes, which are hard to come by when patients are only recruited in a limited geographic region of the country. Because veterans make up a large proportion of the U.S. population and the registry ascertains veteran ALS patients nationwide, it's a unique opportunity to be involved in a study of this magnitude."

Veterans with Severe Mental Illness Seek Medical Treatment over Psychiatric Treatment

Veterans with severe mental illness (SMI) receive more medical treatment than psychiatric treatment in VA medical clinics, according to a study by Durham VA researchers published in the June issue of *Psychiatric Services**.

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**HSR&D Center of Excellence in Primary Care • Women's Health Research Program
Program on the Medical Encounter & Palliative Care**

The study, conducted by Hayden Bosworth, Ph.D., Patrick Calhoun, Ph.D., Karen Stechuchak, M.S., and Marian Butterfield, M.D., all of the Durham VA's Center for Health Services Research in Primary Care, set out to "examine the relationship between specific health risk behaviors and use of health care services in a cohort of veterans with severe mental illness."

Drawing from a larger study, the researchers examined 396 veterans with a primary diagnosis of SMI, which included schizophrenia, schizoaffective disorder, bipolar disorder, or posttraumatic stress disorder (PTSD) for human immunodeficiency virus (HIV) risk behaviors. These risk behaviors included lifetime intravenous drug use and crack cocaine, sexual risk behavior, and current alcohol use disorder. The researchers then examined this group's use of VA health care services. The researchers found that veterans who had lifetime histories of intravenous drug use had increased use of outpatient services, and that veterans who were current alcohol users showed decrease use of outpatient services. Veterans with PTSD were greater users of outpatient medical services over the follow-up year than veterans with schizophrenia-spectrum disorders.

Though veterans with service-connected SMI were high users of both medical and psychiatric care, 53% of these veterans were more likely to use medical service care rather than psychiatric service care. The researchers concluded that the SMI veterans' "high rates of health risk behaviors ... contributed to the high rates of use of medical services," especially among intravenous drug users.

The researchers concluded that "As the VA strives to provide cost-efficient health care to veterans with severe mental illness, understanding veterans' patterns of VA health service use and the relationship of health risk behaviors to, and use of, medical and psychiatric services is crucial. The high rates of health risk behaviors we observed—and related health care use—may provide an opportunity for educational efforts targeting healthier lifestyles for veterans with severe mental illness."

*Bosworth HB, Calhoun PS, Stechuchak KM, Butterfield MI. "Use of Psychiatric and Medical Health Care by Veterans With Severe Mental Illness" *Psychiatric Services* 2004 (June); 55(6):708-710.

Depression Care Management and Diabetes-Related Outcomes

Can effective care for patients with major depression improve affective symptoms and functional status while providing indirect benefits on adherence to self-care regimens and co-existing medical illness outcomes, such as diabetes mellitus? That is what lead researcher John W. Williams, Jr., M.D., M.H.Sc., of Durham's HSR&D Center of Excellence in Primary Care, and his research colleagues asked in a study published in the June 15 issue of *Annals of Internal Medicine**. Approximately 1800 patients with major depression, age 60

years or older, from seven sites in five states were enrolled in the study. Of these patients, 417 stated that they had been diagnosed or treated for high blood sugar or diabetes in the past three years. Patients were randomly assigned to an intervention group that enhanced usual care by adding a depression clinical care specialist who worked collaboratively with the physician, or were assigned to usual care. Participants in the intervention group were given an initial choice of an antidepressant or six-to-eight brief sessions of structured psychotherapy for depression, and their treatment followed for up to 12 months.

The researchers found that "for patients with and without diabetes mellitus, depression was significantly less severe for those in the intervention group at all follow-up points," with "positive effects on overall health-related functional status" appearing later. The intervention worked equally well for patients with or without diabetes mellitus.

The researchers concluded that a collaborative care intervention program for late-life depression in primary care "improved the quality of depression care, as well as affective and functional status outcomes in older adults with major depression or dysthymia and coexisting diabetes mellitus," with positive effects on depressive symptoms appearing early. "These results are encouraging," stated the researchers, "because some trials have found that chronic medical illness moderates the effectiveness of depression treatments." It was also found that the intervention improved mental and physical functioning, though effects were modest and appeared later, with benefits for symptoms and functional status increasing with time.

"A major goal of clinicians caring for older adults is to maximize functioning," stated the researchers. "While the collaborative, stepped-care management intervention used in the current study had limited benefits for diabetes outcomes, the intervention did improve functional status in older adults with coexisting depression and diabetes."

*Williams JW Jr, Katon W, Lin EHB, Noel PH, Worchel J, Cornell J, Harpole L, Fultz BA, Hunkeler MA, Mika VS, and Unutzer J, for the IMPACT Investigators. "The effectiveness of depression care management on diabetes-related outcomes in older patients" *Annals of Internal Medicine* 2004 (June 15); 140(12):1015-1024.

Racial Differences in Osteoarthritis Medication Use and Perceived Efficacy

African-American veterans with osteoarthritis (OA) had somewhat more favorable perceptions of their current medications compared to Caucasians, though overall ratings of medication helpfulness were low, according to a recent study* of perceptions of efficacy of analgesic and anti-inflammatory pain medications.

The researchers, Kelli Dominick, Ph.D., Hayden Bosworth, Ph.D., and colleagues drew their sample of 202 patients diagnosed with OA, 141 Caucasians and 61 African-

Americans, from the Durham VA Medical Center. Of these, 156 were taking some over-the-counter or prescription analgesic or anti-inflammatory drug. This group was asked to rate the helpfulness of each prescription or over-the-counter analgesic/anti-inflammatory pain medication they used for their OA.

“Assessing a patient’s perception of a medication’s helpfulness is a clinically useful measure that could have implications for patient adherence and continuation of that medication’s use,” says Dr. Dominick, the lead researcher of the study.

The researchers found the mean patient rating of medication helpfulness to be low, which, according to some studies, “may contribute to rates of early discontinuation.” African-Americans reported higher OA severity than Caucasians, but also had more favorable perceptions of their medication efficacy than Whites.

Other factors contributed to medication efficacy among patients. Patients taking three or more analgesic/anti-inflammatory drugs had greater perceptions of medication efficacy than those patients taking fewer drugs, suggesting that certain medication combinations may be more effective or that some patients have a general preference for using medications to treat arthritis symptoms. Patients who reported greater OA severity rated medications as less effective than those reporting less OA severity.

The authors concluded that “additional research is needed to examine factors related to perceptions of poor medication efficacy.” Furthermore, “Qualitative investigations may help to identify cognitive, social, and cultural factors that may influence perceptions of drug helpfulness in different racial and ethnic groups.”

*Dominick KL, Bosworth HB, Hsieh JB, Moser BK. “Racial Differences in analgesic/Anti-Inflammatory Medication Use and Perceptions of Efficacy” *Journal of the National Medical Association* 2004 (July); 96(7):928-932.

Race and Colorectal Cancer Screening

With colorectal cancer incidence and mortality higher among blacks than whites, both nationally and North Carolina, Deborah Fisher, M.D., and Dawn Provenzale, M.D., and their colleagues, examined whether colorectal cancer screening rates are different between blacks and whites in a study published in the January/February issue of the *North Carolina Medical Journal**.

The study involving 598 subjects (59% white and 41% black), confirmed previous studies of low colorectal screening rates, but found that race was not a significant determinant of current colorectal screening behavior. The researchers found that income and age were associated with colorectal screening behavior. The strongest predictors for colorectal screening adherence were “having a regular doctor and participating in general medical exams,” with 53% of those

with a regular doctor and only 17% of those without a regular doctor receiving colorectal screening, respectively.

The researchers also noted as other studies have found that having health insurance, increasing age, income, and education were associated with subjects’ participation in colorectal cancer screening, as were healthy behaviors of non-smoking status, seatbelt use, physical activity, increased fruit and vegetable consumption, and recent cholesterol screening.

The researchers stated, “While our study does not provide an explanation for the racial gap in colorectal cancer incidence or mortality, it does offer insights to increase colorectal cancer screening participation for the general population.” The results suggest that health maintenance visits and continuity of a primary care provider may be facilitators of colorectal cancer screening participation. They also state that “the association of higher income and screening behavior is likely related to an increased ability to afford tests, both the costs associated with the test itself and the costs of missing work, traveling to a doctor’s office and related expenses.”

The researchers concluded that their study demonstrates that there are continued financial barriers, and supports the importance of factors related to the primary care setting. They noted that “Future directions include testing interventions that increase continuity of primary care and health maintenance visits.”

*Fisher DA, Dougherty K, Martin C, Galanko J, Provenzale D, Sandler RS. “Race and colorectal cancer screening: A population-based study in North Carolina” *North Carolina Medical Journal* 2004 (Jan/Feb); 65(1):12-15.

HSR Welcomes New Faculty

Health Services Research would like to welcome two new faculty, Lori A. Orlando, M.D., and Corrine I. Voils, Ph.D. Both Dr. Orlando and Dr. Voils join us after completing a two-year fellowship, with their new appointments beginning July 1st.

Lori A. Orlando

Lori Orlando, M.D., M.H.Sc., first came to HSR two years ago as an Agency for Healthcare Research and Quality-funded fellow. During her fellowship she pursued and completed her M.H.Sc. from Duke University.

Working with David Matchar, M.D., Dr. Orlando focused on decision modeling. “Decision modeling allows you to create a virtual clinical trial by generating a patient population based upon available clinical and epidemiological data and then assessing the impact of different clinical strategies on the population. These techniques are particularly useful when performing a clinical trial is either impractical or unethical, and we can use the results to help identify and focus our research on areas that might have the greatest impact on patient outcomes,” says Dr. Orlando.

During this time, Dr. Orlando created a decision model to

look at strategies for initiating triptans, the most effective class of drugs for managing migraine headaches, in individuals who are at risk for cardiac events. According to Dr. Orlando, "During post-clinical trial monitoring triptans were associated with heart attacks, so we know to avoid these drugs in individuals with known heart disease. However, the best strategy for initiating triptans in those who are at risk, but do not yet have known heart disease, is not clear. We need to find out what the best management strategy would be for this rapidly increasing segment of the migraineur population."

After creating the model, she found that the role for stress testing was limited to those who already have such a high risk for heart disease that they should be getting tested anyway. In everyone else, triptans can be offered without the need for cardiac tests.

"My next step is to develop a decision model of chronic kidney disease, which will include therapeutic interventions as well as the interactions between internist and nephrologists," says Dr. Orlando. "I want to examine what nephrologists are doing that the internists aren't, and what medical actions really make a difference."

Now a member of HSR's faculty, Dr. Orlando will continue to focus her research on chronic kidney disease as well as work with Dr. Matchar. "I'm in the process of finishing up a project that I started during my fellowship, an epidemiologic study of chronic kidney disease in the Durham VA hospital," says Dr. Orlando. "I'm examining what happens at the clinic visits, trying to determine what predicts disease progression or disease improvement, and I want to start building a model of chronic kidney disease for the VA population."

Corrine I. Voils

Corrine Voils, Ph.D., begins her faculty appointment as a Merit Review Entry Program awardee — a non-clinician career development award. After receiving her Ph.D. from the University of Kentucky in experimental psychology in 2001, Dr. Voils came to HSR as an Office of Academic affairs-funded post-doctoral fellow in July 2002. During her fellowship, she focused on examining social and personal characteristics that can impact health care access, provider care, and treatment adherence for chronic diseases, specifically for hypertension and hypercholesterolemia. Dr. Voils also worked collaboratively with Dr. Lori Bastian investigating overweight women veterans' motivation to lose weight, as well as provided psychometric expertise for Dr. Karen Steinhauser's scale development projects.

Dr. Voils thinks her fellowship has been invaluable. "One of the areas where I've learned the most is working with the statisticians. I've learned a lot of new statistical techniques that have allowed me to look at research in a different way and ask new questions. Also, interviewing patients and their spouses about their experiences with high blood pressure or high cholesterol has been really informative and allows me

to see how they struggle with these conditions."

From the start of her Career Development Award, Dr. Voils will be collecting pilot data for an intervention study. "It's a spouse-assisted intervention for people with high cholesterol," says Dr. Voils. "I want to get the patient and their spouse to be actively involved in the self-management of the patient's care through information and training in following diets, exercising, taking medications, and dealing with medication side-effects. If it works like I hope it will, I'll then propose a large-scale study, a randomized control trial examining the effectiveness of intervention."

"My long-term research plans are to continue to develop interventions, both on the patient level and the provider level," says Dr. Voils, "improving patient adherence to their providers' guidelines as well as improving providers' adherence to treatment guidelines."

Dr. Hayden Bosworth will be Dr. Voils' primary mentor and Drs. Eugene Oddone and Morris Weinberger will be her secondary mentors for her career development award.

HSR&D Welcomes New M.D. Fellows

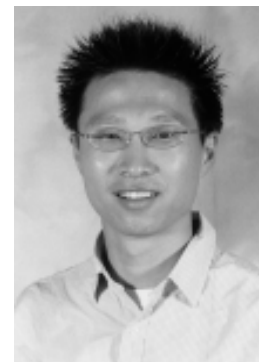
The Center welcomes two new research fellows, Alex Han Cho and Michael James Mugavero, who both began July 1st. They are part of the annual support the Center gives to physicians interested in the structure, process, and effects of healthcare services that can be used to improve the VA medical system and the lives of our veteran patients through two-year medical fellowships.

Alex Han Cho

Alex Han Cho, M.D., is being funded on an Agency for Healthcare Research and Quality fellowship. His research interest is in improving medical outcomes by increasing patient participation in overcoming their illnesses.

"During my residency," states Dr. Cho, "I was distressed by how disconnected many patients seemed from their chronic illnesses. Patients' health depended more on what they did at home than on office visits and hospitalizations. Attempts to discuss exercise, healthier diets, self-care, and smoking cessation were constrained by time and the limits of my expertise, and there were few accessible resources to which patients could be referred." Getting patients to become more involved in their illnesses is an area he sees as "an incompletely explored route to making health care more effective, and possibly, more affordable."

Dr. Cho received a B.A. in Chemistry from Harvard University, graduating *cum laude* in 1996. He received his M.D. from the University of Minnesota Medical School in



2001, and did his residency in Internal Medicine at New York University from 2001 through 2004. During his residency he was a one-year volunteer for the Bellevue/NYU Program for Survivors of Torture Clinic.

"My goals for the fellowship," says Dr. Cho, "are to become firmly grounded in research methods, learning how to sharpen my research questions, and how to design and conduct projects on interventions to change patient health behaviors. Specifically, I'd like to develop an assessment tool to gauge readiness of individual diabetic patients for general categories of interventions, using self-efficacy and stages of change theory. Eventually, I'd also like to craft a menu of possible interventions using community-based partners, available evidence, and an open, patient-driven curriculum design process. I'd then enroll patients in these interventions to test their ability to change behaviors and improve diabetes-specific and other health outcomes."

"I also have a long-term interest in health care financing arrangements that make use of self-management activities, creating economic incentives for healthier behaviors. I want to extend health care into self-care beyond the doctor's office, promoting greater patient self-sufficiency."

Dr. Cho is a member of the American Medical Association, the American College of Physicians, and the Society for General Internal Medicine.

Michael James Mugavero

Michael James Mugavero, M.D., is also being funded on an Agency for Healthcare Research and Quality fellowship. His research interests are infectious diseases and long-term career goals in outcomes and health services research focusing on HIV/AIDS. Dr. Mugavero has just completed a one-year infectious diseases clinical fellowship at Duke University Medical Center.

"My research experience has led me to conclude that formal training in clinical research is essential to my career goals and this fellowship in clinical and health services research will compliment my training in infectious diseases," says Dr. Maguvero. "I hope to complete the Masters of Health Sciences in Clinical Research to provide formal training in research design, research management, and statistical analysis."

Dr. Mugavero was a pre-med major at the University of Notre Dame where he received his B.S. in 1995. He received his M.D. from Vanderbilt University in 1999 and did his four-year residency in Internal Medicine at the University of Alabama at Birmingham from 1999 to 2003, and was the Chief Medical Resident during the fourth year. While at Birmingham, he participated in a three-month research elective in an HIV/AIDS clinic working in secondary data analyses in projects involved with cost analyses, evaluation



of clinical outcomes in the elderly, and an analysis of the durability of antiretroviral regimens in treatment naïve patients.

"During my infectious disease fellowship at Duke, I prepared a proposal to investigate the effectiveness of novel, pamphlet-based counseling, testing, and referral program for diagnosing HIV infection at a community-based healthcare clinic in Durham," says Dr. Mugavero, "and I will continue to work on data analysis of the Coping with HIV/AIDS in rural Southeast (CHASE) project with Dr. Kathryn Whetten of the Health Inequalities Program in Birmingham, Alabama."

"I'm intrigued with the continued evolution and new challenges posed by the HIV/AIDS epidemic. I want to pursue a career in clinical research, with a focus on improving HIV counseling, testing, and referral and prevention broadly, but more specifically among populations that are disproportionately affected," says Dr. Mugavero.

Dr. Mugavero is board certified in Internal medicine and is a member of the Infectious Diseases Society of America. His mentor will be David Edelman, M.D.

Recent Faculty Publications

ORLANDO LA, Orlando RC. "Pathophysiology of GERD: Esophageal Epithelial Defense" *Practical Gastroenterology* 2004; 28(7):14-26, 57.

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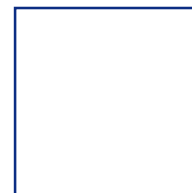
Bushnell CD, **MATCHAR DB**. "Pharmacoeconomics of atrial fibrillation and stroke prevention" *American Journal of Managed Care* 2004 Apr;10(3 Suppl):S66-71.

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Research Update



Department of
Veterans Affairs

Recent Faculty Publications Continued

Adams PC, Arthur MJ, Boyer TD, DeLeve LD, Di Bisceglie AM, Hall M, Levin TR, **PROVENZALE D**, Seeff L. "Screening in liver disease: Report of an AASLD clinical workshop" *Hepatology* 2004 May;39(5):1204-12.

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ZINN S, DUDLEY TK, BOSWORTH HB, Hoenig HM, Duncan PW, Horner RD. "The effect of poststroke cognitive impairment on rehabilitation process and functional outcome" *Archives of Physical Medicine and Rehabilitation*; 2004; 85(7):1084-1090.

YANCY WS Jr, OLSEN MK, Guyton JR, Bakst RP, Westman EC. "A low-carbohydrate, ketogenic diet versus a low-fat diet to treat obesity and hyperlipidemia: A randomized controlled trial" *Annals of Internal Medicine* 2004; 140:769-777.

Research Update is published by the Health Services Research and Development Service, Department of Veterans Affairs Medical Center, Durham. For questions or comments contact Beth Armstrong, Administrative Officer, VAMC (152), 508 Fulton Street, Durham NC, 27705. Telephone: (919) 286-6936, Fax: (919) 416-5836. E-mail: beth.armstrong@duke.edu Web Page: <http://hsrd.durham.med.va.gov/> The Institute's mission is to provide quality information on issues regarding the organization, financing, and delivery of veterans' health care, and to build the epidemiological capacity of the Veterans Health Administration through the generation, synthesis, and dissemination of epidemiological information. The Institute also has a mission to educate health professionals through a spectrum of training grants in the techniques of health services and epidemiological research.